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Pesticide Fact Sheet No. 181: Metiram

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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Office of Pesticide Programs (TS-766C)
Washington, DC 20460

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EPA

Pesticide Fact Sheet

Name of Chemical: METIRAM
Reason for Issuance: REGISTRATION STANDARD
Date Issued: October 3, 1988
Fact Sheet Number: 181

1. DESCRIPTION OF CHEMICAL

Chemical Name: Mixture of 5.2 Parts by Weight (83.9%) of Ammoniates of [ethylenebis (dithiocarbamate)] zinc with 1 part by weight (16.1%) ethylenebis [dithiocarbamic acid], bimolecular and trimolecular cyclic anhydrosulfides and disulfides

Common Name: Metiram

Principal Trade Names: Polyram™, Polyram-Combi™

EPA (Shaughnessy) Code: 014601

Chemical Abstracts Service (CAS) Number: 9006-42-2

Year of Initial Registration: late 1940's

Pesticide Type: Fungicide

Chemical Family: Ethylene bisdithiocarbamate (EBDC)

U.S. and Foreign Producers: FMC and BASF

2. USE PATTERNS AND FORMULATIONS

Registered uses: Terrestrial food crop uses on apples, asparagus, celery, corn (sweet), cotton, cucumber, peanuts, pecans, potatoes (including seed pieces), sugar beets, and tomatoes; Terrestrial nonfood crop uses on tobacco (field and transplants) and roses

Predominant uses: Apples and potatoes

Pests controlled: Foliar fungal diseases of selected fruit, nut, vegetable, field and ornamental crops.

Types of Formulations: Formulation intermediate, dust, and wettable powder.

Types and Method of Application: Foliar application to fruits, vegetables and nuts by aerial equipment, as well as ground equipment. For ground equipment metiram suspensions typically made from a wettable powder, would be applied by means of air blast sprayers or in the case of some row crops by means of tractor mounted boom sprayers.

Application Rates: Terrestrial food crop: 0.3 - 6.4 lb ai/A
Terrestrial nonfood crop: 1.2 - 2.4 lb ai/A

3. SCIENCE FINDINGS

a. Chemical Characteristics

Physical state: solid
Color: Light yellow
Odor: odorless
Vapor Pressure: $<1 \times 10^{-7}$ mbar at 20 C
Molecular Formula: $(C_{16}H_{33}N_{11}S_{16}Zn_3)$

Toxicology Characteristics

Acute Toxicity: All studies required

Major Routes of Exposure: Dermal, Inhalation and oral by ingestion of food residues

Subchronic Toxicity: Inhalation study is adequate, other studies required

Oncogenicity: Studies required

Chronic feeding: Studies required

Metabolism: Studies in rats indicate that the polymer is hydrolyzed and readily absorbed and eliminated in the urine and feces. ETU was one of the metabolites in the urine and bile of rats.

Reproduction: Study required

Teratogenicity & Developmental Toxicity: Studies required

Mutagenicity: Considering only the acceptable studies, the majority of mutagenicity studies on metiram were negative. However, the in vitro sister chromatid exchange assay in Chinese hamster ovary cells was positive and is considered a sensitive test for chromosomal effects. According to the present data, metiram is considered positive for chromosomal

damage. A gene mutation assay is required.

Physiological and Biochemical Characteristics

Metabolism and Persistence in Plants and Animals:

Metabolism of metiram is not completely understood. Additional data are being required in plants and livestock. ETU is a major metabolite of concern.

Environmental Characteristics

Presently only the hydrolysis and photodegradation in soil and in water data requirements on both metiram and ETU were fully satisfied. Metiram has a very limited solubility in water. Metiram in water solution degrades primarily to ETU and other transient degradates. ETU is also a soil degradate of metiram and its formation on soil is enhanced by sunlight. ETU is stable in water at pH 5-9 and under sunlight and the degradation of ETU on soil is not enhanced by sunlight radiation. ETU is the degradate of major environmental concern. There are indications that ETU may leach and enter groundwater. However, additional data are required to complete the groundwater assessment.

Ecological Characteristics

* Metiram has been found to be slightly toxic to birds. Formulated metiram showed that LC50 values for mallard duck and bobwhite quail are both greater than 3712 ppm.

* Based on an acute contact honeybee toxicity study, there is sufficient information to characterize metiram as practically nontoxic to honeybees.

4. TOLERANCE ASSESSMENT

Tolerances, expressed as zinc ethylene bisdithiocarbamate, have been established for residues of metiram in a variety of raw agricultural commodities (40 CFR 180.217 and 180.319).

The toxicology data for metiram are insufficient to determine an Acceptable Daily Intake (ADI) or whether the toxicity observed in the studies is due to metiram or ETU. A three generation rat reproduction study has been used to calculate a Provisional ADI (PADI). Because a NOEL was not reached in the three generation study, an uncertainty factor of 1000 was employed. The PADI for metiram is 0.0003 mg/kg/day.

The theoretical maximum residue contribution (TMRC), based on the assumption that 100 percent of each crop is treated and contains residues at the tolerance level, is 0.009 or approximately 3000 percent of the PADI. Based on a more realistic dietary assessment, using anticipated field residues and estimate of percent crop treated, the estimated average consumption for the U.S. population is 0.00038 mg/kg/day or 122 percent of the PADI.

5. SUMMARY OF REGULATORY POSITIONS

The Agency initiated a Special Review for metiram along with the other EBDC's in June 1987 because of concern about the oncogenic risk to consumers from dietary exposure to ETU from food treated with these pesticides, and the risks of teratogenicity and adverse thyroid effects to applicators and mixer/loaders from exposure to ETU.

- o ETU has been classified as a B_2 oncogen (probable human carcinogen).

- o The Agency will not consider establishment of new food use tolerances for metiram because the current residue chemistry and toxicology data are not sufficient to assess existing tolerances and the toxicology data base is insufficient to determine an ADI and does not allow a decision as to whether observed toxicity is due to metiram or ETU.

- • The Agency will consider the need for establishment of tolerances for ETU and any intermediate metabolites when data are sufficient to permit such decisions.

- • The Agency will not establish any food/feed additive regulations pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) and is deferring action on previously established food/feed additive regulations.

- • Protective clothing labeling for metiram products, as required as a result of the 1982 Decision Document, must be updated.

- • The Agency is requiring reentry data for metiram. In order to remain in compliance with FIFRA, an interim 24-hour reentry interval requirement must be placed on the label of all metiram end-use products registered for agricultural uses, until the required data are submitted and evaluated and any change in this reentry interval is announced.

- • The Agency has screened and reviewed the environmental fate data to determine if metiram/ETU and/or its degradate(s) have the potential to leach into ground water. The Agency has decided that in addition to environmental fate data requirements, a small-scale retrospective ground water monitoring study is also required to define the extent of the ground water problem.

- o While the data gaps are being filled, currently registered manufacturing-use products (MP's) and end-use products (EP's) containing metiram as the sole active ingredient may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. However, new uses will not be registered. Registrants must provide or agree to develop additional data, as specified in the Data Appendices of the Registration Standard, in order to maintain existing registrations.

6. LABELING REQUIREMENTS

All metiram products must bear appropriate labeling as specified in 40 CFR 156.10. Appendix II of the Registration Standard contains information on labeling requirements.

In addition to the above, in order to remain in compliance with FIFRA, the Agency is requiring:

- Protective clothing requirements
- Environmental hazard precautions
- Worker safety rules
- Reentry interval
- Grazing restrictions for apples, pecans, corn (sweet), cotton, peanuts, sugar beets and potato (seed pieces).

7. SUMMARY OF DATA GAPS

Product Chemistry All - Due within 6 months

Technical Grade:
Preliminary analysis of product samples

MUP:
Analysis & certification of product ingredient
Oxidizing or reducing action
Flammability
Explodability
Storage stability
Corrosion characteristics

Toxicology - The last studies are due 12/90

Acute testing
Dermal sensitization
90-Day feeding (rodent and nonrodent)
21-Day subchronic dermal
Chronic toxicity (rodent and nonrodent)
Oncogenicity (rat and mouse)
Teratology (rabbit and rat)
Reproduction (rat)
Mutagenicity (point gene mutation)

Residue Chemistry - Data due 10/88 and 4/89

Nature of the Residue in Plants and Livestock
Analytical Methods
Magnitude of Residue for Variety of Commodities

Environmental Fate - Last studies are due 7/90

Leaching and adsorption/desorption
Field dissipation
Degradation soil
Degradation (soil long-term)
Small-scale retrospective ground water monitoring
Confined rotational crops
Fish accumulation

Reentry Protection - Data due 7/89

Reentry Studies on Foliar and Soil Dissipation

Wildlife and Aquatic Organisms - Last data are due in 12 months

Avian oral toxicity
Freshwater fish toxicity
Acute freshwater invertebrates
Estuarine and marine organism toxicity

ETU Data Requirements

Toxicology

Chronic (rodent and non-rodent) Data due 5/90
Reproduction Data due 12/90

Environmental Fate - Last studies due 7/90

Aerobic and anaerobic soil metabolism
Aerobic aquatic
Lab volatility
Degradation (soil)
Aquatic (sediment)
Degradation (soil long-term)
Small-scale retrospective ground water monitoring study
Fish accumulation

8. CONTACT PERSON AT EPA

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9. DISCLAIMER: The information in this Pesticide Fact Sheet is a summary only and may not be used to satisfy data requirements for pesticide registration and reregistration. The complete Registration Standard for the pesticide may be obtained from the National Technical Information Service. Contact the Product Manager listed above for further information.